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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,533	11/14/2003	Pierre Druilhe	02356.0086	5870

22852 7590 10/18/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,533	DRUILHE ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,8-40 and 42-44* is/are pending in the application.

4a) Of the above claim(s) *1,12-40,43 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,5,8-11 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment filed August 9, 2007 is acknowledged and has been entered. Claims 2, 3, 6, 7 and 41 have been canceled. Claims 5, 8 and 42 have been amended. Claims 1, 4, 5, 8-40 and 42-44 are now pending in the present application.

2. Claims 1, 12-40, 43 and 44 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 25, 2006.

3. It is noted that "Applicant has not relied on the benefit of foreign priority. The filing date of the instant application is May 15, 2002, filing date of PCT/FR02/01637.

4. The Office acknowledges the Deposit Declaration filed August 9, 2007. A cell line disclosed in this application was deposited at the Collection Nationale de Culture de Microorganismes, Paris, France, under Accession Number 1-2671 on May 23, 2001. A cell line disclosed in this application was deposited at the Collection Nationale de Culture de Microorganismes, Paris, France, under Accession Number 1-2672 on May 23, 2001.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 4, 5, 8, 9 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardner et al (Science 1998, 282:1126-1132).

See sequence search result:

RESULT 1 A71622 hypothetical protein PFB0155c - malaria parasite (Plasmodium falciparum) C;Species: Plasmodium falciparum C;Date: 13-Nov-1998 #sequence_revision 13-Nov-1998 #text_change 21-Jul-2000 C;Accession: A71622
R;Gardner, M.J.; Tettelin, H.; Carucci, D.J.; Cummings, L.M.; Aravind, L.; Koonin, E.V.; Shallom, S.; Mason, T.; Yu, K.; Fujii, C.; Pederson, J.; Shen, K.; Jing, J.; Aston, C.; Lai, Z.; Schwartz, D.C.; Pertea, M.; Salzberg, S.; Zhou, L.; Sutton, G.G.; Clayton, R.; White, O.; Smith, H.O.; Fraser, C.M.; Adams, M.D.; Venter, J.C.; Hoffman, S.L. Science 282, 1126-1132, 1998 A;Title: Chromosome 2 sequence of the human malaria parasite Plasmodium falciparum. A;Reference number: A71600; MUID:99021743; PMID:9804551 A;Accession: A71622
A;Status: preliminary; nucleic acid sequence not shown; translation not shown
A;Molecule type: DNA
A;Residues: 1-507 <GAR>
A;Cross-references: UNIPARC:UPI000017B602; GB:AE001376; GB:AE001362; NID:g3845108; PIDN:AAC71821.1; PID:g3845110; TIGR:PFB0155c
A;Experimental source: clone 3D7
C;Genetics:
A;Gene: PFB0155c
Query Match 81.8%; Score 284; DB 2; Length 507;
Best Local Similarity 91.7%; Pred. No. 2.8e-18;
Matches 55; Conservative 1; Mismatches 4; Indels 0; Gaps 0;

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Qy       3 HMHDYIYDDRIYNNDKEKNVIKSDNKNVIKSDNKNDYKKCNKNVIKSDNKNVIKSDNKNV 62
           :|||||||||||||||||||||||||||| | ||||||||||||||||
Db      80 NMHDYIYDDRIYNNDKEKNVIKSDNKNVIKSDNKNVIKSDNKNVIKSDNKNVIKSDNKNV 139
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Since the Patent Office does not have the facilities for examining and comparing applicants' polypeptide with the polypeptide of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed polypeptide and the polypeptide of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

This rejection is maintained for the reasons of record. Applicant's arguments filed August 9, 2007 have been fully considered but they are not persuasive. Applicants have asserted that claim 4 is directed to an isolated or purified polypeptide comprising a peptide sequence corresponding to SEQ ID NO: 3. In addition, Applicant amended claim 5 such that it is now directed to an isolated or purified polypeptide comprising a peptide sequence with at least 40 consecutive amino acids identical to SEQ ID NO: 3 or a peptide sequence with at least 95% identity with SEQ ID NO: 3. Applicants have asserted that Gardner et al. does not anticipate claims 4, 5, 8, 9, and 42 because the polypeptides cited by the Office are not identical to SEQ ID NO: 3, do not have a peptide sequence with at least 40 consecutive amino acids identical to SEQ ID NO: 3, and/or do not have a peptide sequence with at least 95% identity with SEQ 1D NO: 3. Applicants have asserted that the sequence search result provided by the Office, hypothetical protein PFB0155c, disclosed by Gardner et al., appears to have a best local similarity of 91.7% when compared to SEQ ID NO: 3. Applicants have asserted that Gardner et al. fail to teach every aspect of the pending claims since the sequence cited by the Office is not identical to SEQ ID NO: 3, the sequence does not have 40 consecutive amino acids identical to SEQ ID NO: 3, and the sequence does not have at least 95% identity with SEQ ID NO: 3.

However, it should be remembered that the specification teaches "the polypeptide of the invention comprises at least 5 consecutive amino acids identical to one of SEQ ID NOs: 3 to 8" (see p. 4 of specification). Claim 4 is directed to an isolated or purified polypeptide comprising *a peptide sequence* corresponding to SEQ ID NO: 3. Gardner et al discloses *a peptide sequence* (i.e. at least 5 consecutive amino acids) corresponding to SEQ ID NO: 3 (see sequence search

results above). Claim 5 is directed to an isolated or purified polypeptide comprising a) a peptide sequence with at least 40 consecutive amino acids identical to SEQ ID NO: 3 ***or*** *a peptide sequence* with at least 95% identity with SEQ ID NO: 3. Claim 5 is written in the alternative and the prior discloses *a peptide sequence* (i.e. at lest 5 consecutive amino acids) with at least 95% identity with SEQ ID NO: 3 (see sequence search results above).

10. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardner et al (Science 1998, 282:1126-1132) as applied to claims 4, 5, 8, 9 and 42 above, and further in view of Druilhe et al (6191270).

Gardner et al has been described above. Gardner et al teaches the claimed invention except for the recitation of the support (i.e. microspheres, microparticles of latex beads, polyphosphoglycan microparticles (PGLA), or polystyrene microparticles) on which said antigen is adsorbed.

However, Druilhe et al teaches use of isolated and purified polypeptides from *P. falciparum* (abstract). Druilhe et al teaches that the antigens or peptides according to the invention may be coupled to traditional supports or adsorbed on such supports, in particular latex or polystyrene microspheres or beads (Summary of the Invention, paragraph 73). "Lastly, the invention covers a method of immunization of an individual likely to be infected by P. falciparum, by injection of a peptide molecule or an oligomer as described above, alone or in combination with other types of molecules capable of protecting the said individual against subsequent infection; the polypeptide or antigenic molecule or the natural or recombinant lipopeptides are either used alone or adsorbed or coupled to latex or polystyrene micro-spheres or beads." (Summary of the Invention, paragraph 84)

"Lastly, the invention covers a method of immunization of an individual likely to be infected by P. falciparum, by injection of a peptide molecule or an oligomer as described above, alone or in combination with other types of molecules capable of protecting the said individual against subsequent infection; the polypeptide or antigenic molecule or the natural or recombinant lipopeptides are either used alone or adsorbed or coupled to latex or polystyrene micro-spheres or beads." (Detailed Description, paragraph 70)

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the teachings of Gardner et al and Druilhe et al with the reasonable expectation of making a composition (antigenic conjugate) comprising an isolated or purified polypeptide and a support. Druilhe et al teaches that the best results (i.e. protection of mice) were obtained by immunization with the recombinants, or antigens prepared according to the invention, adsorbed on latex or polystyrene microspheres 0.5 .mu.m in diameter (Detailed Description, paragraph 70). The claimed invention is prima facie obvious in view of the combined teachings of Gardner et al in view of Druilhe et al absent any convincing evidence to the contrary.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the

examiner's acting supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
October 15, 2007